

## The use of BCG\*

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*La belle province has lost one of her best-known sons. Dr. Armand Frappier, a pioneer in preventive medicine, died Dec. 18, 1991, at the age of 87. His many accomplishments, which earned him international recognition, were highlighted in a CMAJ Profile (1980; 123: 807) that said in part: "It's to the insight, tenacity and scientific flair of Dr. Armand Frappier that we owe the use of Bacille Calmette-Guérin (BCG vaccine) in the prevention of tuberculosis in Canada." In a quiet tribute we reprint this 1948 paper by Dr. Frappier and his colleague Dr. Roland Guy on the 25-year history of the use of BCG.*

As early as 1926, Canadian workers hurried in checking over the work of Calmette and his colleagues<sup>1</sup> on BCG. This was undertaken only two years after their announcement of the results obtained in 217 Parisian children vaccinated with BCG from 1921 to 1924. It is worthwhile mentioning here that the 25th anniversary of this important scientific and medical event is being celebrated in Paris, where the First International Congress on BCG is being held under the combined sponsorship of the Pasteur Institute and the French Government.

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## The history of BCG vaccine in Canada — Results — Value of BCG

In 1925, the National Research Council of Canada created an Associate Committee for research on tuberculosis and BCG, by which the University of Montreal was entrusted with the work of preparing BCG and studying its innocuousness and effectiveness in laboratory animals and new born children from tuberculous environment. Professor J. A. Baudouin,<sup>2</sup> of the Medical Faculty of the same University was the originator, in 1926, of oral BCG vaccination of newborn in Canada and in America.

Professor A. C. Rankin, of Alberta and Dr. E. A. Watson, of Ottawa, also under the auspices of the National Research Council of Canada, undertook the study of BCG vaccination of the bovines. Contrary to Watson, Rankin<sup>3</sup> has obtained definite protection with BCG in cattle thus confirming the previous works of Calmette, Guérin, Richart and Boissière.<sup>4</sup> Identical results were later published by Buxton, Griffin and coworkers.<sup>5,6</sup> Starting in 1933, Frappier and his collaborators,<sup>7 to 16</sup> have confirmed the innocuousness of BCG for laboratory animals and humans, and its protective value in the guinea-pig; the same authors have also studied the development and the evolution of the tuberculin hypersensitivity in guinea-pigs and humans vaccinated with BCG, the value and practicability of new modes of vaccination, the intratuberculin allergy and the stability of BCG vaccine.

In 1933, Dr. R. G. Ferguson,<sup>17,18</sup> of Saskatchewan, initiated his study of intradermal BCG vaccination of Indian children and, later on, of white adults, nurses and employees of hospitals and sanatoria, found negative to tuberculin. From the beginning, Dr. Ferguson used the BCG vaccine prepared at the University of Montreal. The works of Baudouin and Ferguson are among the most important and conclusive statistical studies ever published on the value of BCG. Their results show that, in tuberculous surroundings, BCG vaccine can afford an appreciable protection against tuberculosis (from 72 to 80%) either in newborn or adults, and that this protection extends over a remarkable period of time, i.e., at least 5 years after vaccination (Tables I and II).

## The BCG Vaccination Service in Canada — Affiliated services — Research

All of the above results, as well as the scrupulous technique employed in the laboratories of the BCG Vaccination Service of the Institute of Microbiology and Hygiene of the University of Montreal, which is delivering BCG throughout Canada, Australia and Newfoundland, have progressively given confidence to physicians, health officers and the public in general in Canada towards BCG vaccination. During the period extending from 1926 to 1948, over 200,000 persons have been BCG vaccinated in Canada, most of them in the Province of Quebec. At the present time, over 20% of the newborn in the Province of Quebec are yearly vaccinated with BCG.

The BCG vaccine is delivered free of

charge to subjects to be vaccinated. The BCG Vaccination Service is supported by special grants from the Department of Health of the Province of Quebec which took over, in 1938, the financial assistance till then shared by the National Research Council and the Medical Faculty of the University of Montreal.

Brief mention should be made of the activities of the BCG Clinic of Montreal, under the direction of Dr. Guilbeault, which was established in 1935 by the Provincial Ministry of Health, for the isolation, vaccination and re-vaccination of children born in tuberculous families. Acknowledgement should be made also of the work accomplished in the obstetrical clinics of the numerous hospitals in the province and especially of that in the Social Service of Ste-Justine Hospital in Montreal, under the direction of Dr. Lapierre, whose col-

TABLE I.  
RESULTS OF PROFESSOR J. A. BAUDOUIN (MONTREAL)  
1926 - 1947  
TUBERCULOSIS MORTALITY RATE PER 1,000

<i>Groups</i>	<i>Total number in each group</i>	<i>6 to 12 months</i>	<i>1 to 4 years</i>	<i>5 years and over</i>	<i>All ages</i>
New-born vaccinated with BCG, oral method .....	1,187	6	12	0	15
Non-vaccinated controls .....	1,606	21	29	2	49

TABLE II.  
RESULTS OF DR. R. G. FERGUSON (SASKATCHEWAN)  
1938 - 1946  
PERCENTAGE OF MORBIDITY BY TUBERCULOSIS

<i>Groups</i>	<i>Total number in each group</i>	<i>Number of tuberculosis cases</i>	<i>% of morbidity by tuberculosis</i>
Nurses vaccinated with BCG, intradermal method .....	1,005	9	0.895
Hospital personnel vaccinated with BCG .....	470	9	1.92
Nurses negative to tuberculin not vaccinated (controls) .....	1,368	55	4.02
Hospital personnel negative to tuberculin not vaccinated (controls) .....	274	32	11.67

laboration enabled us to study the development of post-vaccinal allergy as well as new modes of vaccination.

We have also studied the various methods of vaccination with Calmette's vaccine at the BCG Clinic of Montreal, in Indian Agencies and in schools supervised by the Health Unit of Verchères. In the latter case, we have performed extensive experiments, with the collaboration of Dr. Roy,<sup>19,20</sup> on the development of tuberculin allergy along with the local and systematic reactions to vaccination. We have also carried on the same kind of experiments in St-Jean-de-Dieu mental hospital in Montreal.

Most of the vaccinations with BCG in the Province of Quebec were performed by the oral method, consisting of three doses of 10 mgm. of BCG given on alternate days in the first 10 days of life. Very few adults were vaccinated, exception being made for hospitals and sanatorium personnel. On the other hand, Dr. R. G. Ferguson and his associates in Saskatchewan have worked out the intradermal route for vaccination, using 2/10 mgm., divided into 2 injections.

### **Discussion on the various methods of vaccination — Techniques**

The disadvantages of the oral route are the slow induction of tuberculin allergy (3 to 6 months) and the impossibility of ascertaining whether the vaccine has been successfully absorbed. Vomiting or any cause limiting the absorption by the intestinal tract are hindering factors of efficiency in oral BCG vaccine. The advantages of the oral route are that it is easily accepted and does not produce any local or general reactions except in a few instances, where moderate enlargement of the cervical glands is noted. No hyperthermia is attributed to oral BCG. In some cases, a mild diarrhea may follow, which subsides rapidly without any medication.

The disadvantages of the intradermal and subcutaneous methods are the eventual formation of cold abscesses of a degree varying according to the perfection in the technique of injection, as Törnell,<sup>21</sup> and other authors have recently emphasized. When drainage is necessary, these abscesses must not be incised but punctured, in order to avoid scar formation. Nearly 100% of subjects thus vaccinated become tuberculin allergic within two or three months after vaccination.

When testing with tuberculin, our first

screening is made with the Vollmer patch test, then the negatives are tested with the Mantoux, using at least 1 mgm. tuberculin O.T., or 5 mgm. P.P.D.

Although the oral route is still in use in most of the clinics of the Province of Quebec, we have introduced the scarification method, proposed by Nègre and Bretey,<sup>22</sup> which is gradually replacing the oral method. The subcutaneous route is not recommended. A few authors still prefer the intradermal method for its easiness and rapidity. They use it for children or adult vaccination, less in newborn, but they have to deal with occasional scar formation, which, in certain regions, may constitute a handicap to the wide acceptance of BCG vaccination. We have made an extensive study of the allergizing value of the multiple puncture or Rosenthal method<sup>23 to 26</sup> and the scarification method, both in newborn and adults. We advocate, for both these methods, the use of an emulsion of vaccine containing 60 mgm. per c.c. Experience has shown us that, in order to obtain a high and durable degree of allergy, 40 to 60 punctures should be performed for the former method of vaccination and, for the latter, 4 to 6 scarifications, newborn receiving the smaller doses. The sites of choice, in either case, are, for children and adults: the lower back in the lumbar region, dividing equally the punctures and the scarifications on each side of the vertebral column; newborn are preferably vaccinated on the upper deltoid region or in the thoraco-axillary space. The reason for recommending the lumbar region is based on the occasional scar formation following the vaccination of an individual already allergic or being in the state of the so-called infratuberculin allergy, which will be discussed briefly later on.

Both techniques of multiple puncture and scarifications are easily performed. BCG vaccination by the method of Rosenthal is similar to the technique used for smallpox vaccination. Bleeding should be avoided, although pinpoint haemorrhages may be noted at the sites of the punctures. As to the method of scarifications scratches of 1 cm. long are made with a needle similar to that used for the puncture method, through drops of BCG spaced 1 cm. one from another. The scratch must be vigorous enough to produce slight bleeding by one single stroke. The oozing, having appeared after a few seconds, is diluted in the vaccine with the point of the needle. Two sterile compresses, moistened with a small quanti-

ty of vaccine, are then applied on the scarifications. They are removed the following day.

The allergizing properties of both methods compare favourably, providing one uses sufficient dosage of vaccine and a number of punctures and scarifications which allow equal surfaces of entry. In non-allergic vaccinated individuals, local reactions with both methods offer the same pattern. They are noted two weeks after vaccination and appear as red pinsize or linear cheloid-like nodules; no abscess formation is noted; swelling of local lymph-nodes is very rarely observed.

Experimentally and clinically, it is well proved that the dosage of the vaccine and the multiplication of the portals of entry are of considerable importance in the earliness, the intensity, and the duration of the allergy. We have confirmed the contention of Nègre and Bretey and other authors, in guinea-pigs and in humans, as to the ideal concentration of BCG, which should be at least 60 mgm. per c.c. of emulsion, for performing regularly successful vaccinations by the transcutaneous methods.

The scarification method, no doubt, offers appreciable advantages over other routes of introducing BCG vaccine. It should be of great help in popularizing BCG vaccination because of its greater simplicity. As with the multiple puncture method, early allergy is induced and no abscess or scar formation is observed.

Serial tuberculin testing before vaccination must be done properly, using as the last test a strong dose of tuberculin in order to trace true non-allergic subjects. Vaccination of weakly allergic individuals, that is, those negative only to a low concentration of tuberculin, for example to Vollmer patch test or P.P.D. tuberculin 2/100 mgm., will bring on intensified and accelerated local reactions in one week, a local modified Koch phenomenon. The local reaction appears in the few hours following vaccination. It may become purulent and scar tissue is the usual sequel.

### **The persistence of tuberculin hypersensitivity after BCG vaccination**

As yet, the knowledge concerning the persistence of tuberculin hypersensitivity due solely to BCG vaccination is very limited, and owing to the present distribution of tuberculous infection, it is difficult to be

appreciated. There always exists the possibility of a sub-clinical natural infection, superadded to that of BCG and maintaining the allergy. That probably explains why, on that subject, the authors are at variance: some state that the allergy fades away in two or three years and others say that it persists even ten years after BCG vaccination.<sup>27 to 32</sup>

The Scandinavian authors insist upon the revaccination of all subjects who, having been previously vaccinated by the intradermal method are found negative to tuberculin six weeks later. It is granted that a positive reaction to tuberculin after vaccination is, for the moment, the only criterion of the absorption of the vaccine and of the probable building up of a state of resistance. However, with wide-scale BCG vaccination, this practice of immediate tuberculin control might seem somewhat costly and useless, if one thinks that, for the sole detection of a small percentage of negative subjects, all those vaccinated should be submitted to the immediate tuberculin control tests. With the use of modern methods of vaccinations, namely intradermal or transcutaneous, nearly 100% of positive reactions are obtained within six weeks. It appears unnecessary to test systematically all such vaccinated subjects who may be considered from a practical point of view, already allergic at the end of the above-mentioned period. Moreover, when the tuberculin reaction is negative in a newborn, it should be remembered that the cutaneous reactivity at this age is not always reliable. After six months of age, the skin of the child will show more accurate hypersensitivity.

Obviously, in order to obtain an early and prolonged allergy, one should use appropriate concentrations and dosage of vaccine. From a practical point of view, when using modern methods of vaccination and the appropriate concentration and dosage of vaccine, the first collective tuberculin control of the subjects thus previously vaccinated could be relayed until about two years after the last vaccination. There is, however, no objection to the practice of the yearly control when necessary.

A few physicians contend that BCG would sensitize the organism to the point that it would react later to the natural tuberculous infection in a more destructive manner. Such a tuberculous disease would present the "reinfection" or the "adult" type of tuberculosis. However, experimental and clinical facts do not support this contention;

the hypersensitivity to tuberculin and to bacillary proteins, as conferred by BCG, is of a weaker type than that conferred by virulent bacilli; with the dosage of BCG used for human vaccination, there can be no fear of producing a tissue hypersensitivity similar to that which is acquired by the organism following a virulent primary infection; radiologic examination shows that the primary tuberculous infection in the vaccinated subjects is considerably reduced in importance; statistical data establish that the tuberculous morbidity is reduced as well as the mortality in BCG vaccinated subjects; clinically, tuberculosis is less severe when it appears in vaccinated subjects. Moreover, at present many phthisiologists, radiologists and pathologists are of the opinion that the concepts of "reinfection" or "adult" type of tuberculosis are to be revised, because phthisiogenesis cannot be explained in so simple a manner.

### **Infratuberculin allergy — The BCG scarification test**

In 1945, in the course of investigations on the respective allergizing value of the multiple puncture and scarification methods, we noticed an important percentage of individuals of all ages, who, although negative to a strong dose of tuberculin (5 mgm. tuberculin P.P.D.), presented, when vaccinated with BCG vaccine, in the 24 to 48 hours immediately following vaccination, accelerated and intensified local reactions, somewhat similar to the reactions observed in "weakly allergic" subjects. This type of allergy to total bacillary bodies has been recently called by South American authors,<sup>33</sup> "the infratuberculin allergy". We have gone into the investigation, in a rural health unit and in Indian reserves, of the incidence of infratuberculin allergy. Our results correspond closely with the figures of Rosemberg,<sup>34</sup> of Brazil, and Andenoes,<sup>35</sup> of Scandinavia. This incidence may be as high as 20% in subjects not BCG vaccinated. It is three times as high in subjects previously vaccinated with BCG and who have become anergic.

Another characteristic of this infratuberculin allergy is the production of the Baldwin-Gardner-Willis-Sayé phenomenon, which consists in a remarkable shortening of the pre-allergic period following BCG vaccination. In our series of investigations, this phenomenon has been observed in 100% of cases. But it is not a constant phe-

nomenon, since Saenz and Canetti<sup>36,37</sup> reproduced it in only 43% of cases, and Coste, Barnaud and Hervet<sup>38</sup> in 83% and Rosemberg in 66% of cases. The differences in percentages may very well be due, not to the inconsistency of the phenomenon, but to the more or less weak dose of tuberculin used in testing infratuberculin allergic subjects.

In the course of these studies, we wondered whether a scarification test for total bacillary bodies like BCG could not be made into a practical test for detecting all tuberculous infection, and so replace the serial tuberculin tests which prove somewhat time- and money-consuming. Various concentrations of BCG have been experimented with in order to find the optimal concentration capable, on the one hand, of revealing a modified Koch reaction in the least sensitive individuals, but incapable, on the other hand, of provoking too intense reactions in strongly allergic individuals. Further research is needed to confirm our preliminary contention of an optimal concentration located between 10 and 25 mgm. of BCG per c.c. The technique is much the same as the Von Pirquet reaction, save that BCG is substituted for tuberculin. The ideal time of reading is 48 hours after the test, when comparison between the BCG and the control scratches is easily established, the traumatic reaction having practically disappeared. We used live BCG, since this test might then constitute a booster dose in reinforcing the resistance of the infratuberculin allergic as well as the "weakly allergic" subjects.

A similar but intradermal test, reported by Bueno, is presently used in Brazil, where de Assis<sup>39</sup> uses 1/10 mgm. of killed BCG. In France, recently Chaussin<sup>40</sup> has also advocated the intradermal route and reported para-allergic reactions. With leprosy<sup>41</sup> Ustvedt,<sup>42</sup> in Norway, has recently used a puncture method which is called "BCG diagnostic".

### **Integration of the BCG vaccination in the program of tuberculosis control**

As Calmette wrote twenty years ago, BCG vaccination affords an appreciable but relative resistance and should not be substituted for any other method of tuberculosis control, but it must be added to the anti-tuberculous armament as a specific weapon which will certainly help in reducing, not

only mortality, but also morbidity by tuberculosis. May we insist on the timely advisability of rationalizing the use of BCG vaccine. We have made experimental attempts in the study of a practical plan for the use of BCG vaccine in the field of public health in the Province of Quebec. This plan has been worked out among the Indians under the auspices of the Federal Department of Health and Welfare, Indian Section, as well as in the Health Unit of Verchères, of the Province of Quebec, with the co-operation of Dr. Roy.

A BCG vaccination program begins with a tuberculin survey, since no positive subject needs BCG. Taking that into account, it is easily seen that such a tuberculin survey should be co-ordinated with a program of detection of tuberculosis in the population. It is obvious that this co-ordination is necessary between the various institutions concerned with BCG vaccination and with case-finding. Some sort of authority should be entrusted with the power of organizing, controlling the BCG vaccination in every province, and well co-ordinating the efforts of different social services and anti-tuberculosis bodies interested in BCG vaccination.

We have proceeded to the tuberculin testing of different communities in the Province of Quebec, starting with the school population. School children found negative were vaccinated at once. Those found positive were directed to the tuberculosis clinics for a thorough examination and their relations called to the same clinics for a similar check-up. Newborn were systematically vaccinated by the attending physicians or the nursing personnel. Every two years, a tuberculin survey is made and revaccination of anergic subjects performed. Hospitals and sanatoria are also urged to make BCG vaccination compulsory for their personnel who are negative to tuberculin.

We consider that the school children give an excellent picture of the incidence of tuberculosis among our population. By testing them with tuberculin, two aims are reached: first, the vaccination of the negatives which should be done systematically in our surroundings; second, and this is the most important, an investigation into the families and surroundings of the positives, by means of a tuberculin survey: the negatives are BCG vaccinated and the positives examined. An appeal is made to those families of the positive children, either by letter or by direct contact through the social

services, and they are urged to come to the BCG clinics or dispensaries in order to be tested, examined and vaccinated, if necessary. Those who do not answer this call are visited at home by the social services and offered transportation to the clinic for examination.

All newborn from tuberculous families should be isolated in a BCG clinic where they are vaccinated. They are brought back into their family only when found positive to tuberculin. For ten years, Dr. Guilbeault, at the BCG Clinic of Montreal, has followed up and surveyed over 500 of such children, isolated at birth from tuberculous families and who have thereafter lived in contact with proved cases. None of them has yet died of tuberculosis and only three have developed a mild clinical disease. Such results show that BCG vaccination, completed by isolation and follow-up, may contribute in realizing nearly 100% protection.

It is obvious that a co-ordinated anti-tuberculous program integrating BCG vaccination will realize an economy of time, effort and lives. No doubt that tuberculin surveys of the families reach into the nest of tuberculosis and that it should constitute the foundation in the detection of tuberculosis and should be continued with BCG vaccination. At the same time, it helps provide education for those families and makes them fully conscious of the dangers of tuberculosis.

Those to be vaccinated first are the individuals in more immediate danger of infection. But one must remember that tuberculosis is a most insidious disease: nobody knows the mode, the time, the dose and the future of his potential tuberculous infection. No community may be kept closed to all imports from outside in a world where population movements are so facilitated by transportation. On the other hand, even radiologic and more elaborate clinical investigations cannot detect all cases of tuberculosis. In such instances, the ignored tuberculous patient, even if he does not bring massive infection to the community, can originate sporadic epidemics of tuberculosis and remain an unsuspected reservoir. Phthisiologists agree that nearly 50% of the tuberculous cases contract the disease from unknown sources. No doubt, mortality rates have been reduced considerably by non-specific control measures, but morbidity rates have not, in general, shown the same decrease. BCG vaccination would institute

an appreciable protection against such insidious contacts and then contribute in further reducing tuberculous morbidity and morality.

As a conclusion, let us adapt a phrase credited to King Edward VII of England: "If tuberculosis is preventable, why not prevent it?"

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## Résumé

Les auteurs rappellent l'histoire du B.C.G au Canada et les résultats obtenus par le professeur Baudouin de Montréal et ceux du Dr Ferguson de Saskatchewan. Ces travaux montrent que la vaccination a apporté une protection efficace de 72% à 80% pendant 5 ans dans des milieux tuberculeux. De 1926 à 1948, 206,000 personnes ont été vaccinées au Canada et chaque année 20% des nouveaux-nés du Québec le sont. Les auteurs préconisent la scarification à la région lombaire comme méthode idéale de vaccination. Les voies intra-dermique et sous-cutanée causent des abcès et la voie orale est trop lente. Les épreuves à la tuberculine doivent précéder l'administration de B.C.G. Le seul critère actuel pour contrôler la résistance de l'organisme et l'efficacité de la vaccination nous est fourni par ces épreuves. Cependant les auteurs ne jugent pas nécessaire de faire systématiquement cette épreuve au bout de six semaines car avec les méthodes modernes de vaccination on peut s'attendre à presque 100% de réactions positives. La durée de l'hypersensibilité à la tuberculine est encore sujette à débat. Les auteurs résument leur expérience avec l'emploi du B.C.G. en scarification comme une épreuve pouvant remplacer la tuberculine dans le dépistage des infections tuberculeuses. Cette allergie aux bacilles complets a été appelée allergie à l'infratuberculine par des auteurs de l'Amérique du Sud. Les auteurs insistent sur l'importance d'établir un programme pour régler la distribution du B.C.G. parmi la population et citent les travaux actuellement faits dans la province de Québec. — Yves Prevost